

### DETAILED ACTION

1. Claims 1-19 and 21-24 are currently pending in the instant application.

#### *Lack of Unity*

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention (which will be rejoined with the pending compound claims) to which the claims must be restricted:

Group I, claims 1, 3-7, 10 and 12-15, drawn to a method of preparing compounds of formula (III), not required for Groups II-VI, classified in various subclasses of classes 558, 564, 544, 546, 548, and 549. A further election of a single disclosed compound of formula (III) is required if this group is elected.

Group II, claims 2-9, 11-14 and 16-19, drawn to a method of preparing compounds of formula (IIIa), not required for Groups I, and III-VI, classified in various subclasses of classes 558, 564, 544, 546, 548, and 549. A further election of a single disclosed compound of formula (IIIa) is required if this group is elected.

Group III, claim 21, drawn to compounds of formula (III), not required for Groups I, II, and IV-VI, classified in various subclasses of classes 558, 564, 544, 546, 548, and 549. A further election of a single disclosed compound of formula (III) is required if this group is elected.

Group IV, claim 22, drawn to compounds of formula (V), not required for Groups I-III, V and VI, classified in class 514, subclasses 336+. A further election of a single disclosed compound of formula (V) is required if this group is elected.

Group V claim 23, drawn to compounds of formula (IIIa), not required for Groups I – IV and VI, classified in various subclasses of classes 558, 564, 544, 546, 548, and 549. A further election of a single disclosed compound of formula (IIIa) is required if this group is elected.

Group VI, claim 24, drawn to compounds of formula (Va), not required for Groups I-V, classified in various subclasses of classes 558, 564, 544, 546, 548, and 549. A further election of a single disclosed compound of formula (Va) is

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required if this group is elected.

3. **In addition to an election of one of the above Groups, restriction is further required as follows:**

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other members obvious under 35 U.S.C. 103.

4. Where an election of any one of Groups I-VI is made, an election of a single disclosed compound of formula III, IIIa, V, or Va (in the specification) is further required, including an exact definition of each substituent on the base molecule, wherein a **single member** at each substituent group or moiety is selected. For example, the base compound III has the substituent group A, wherein A is recited to be any one of  $C(=O)OR^1$ ,  $C(=O)N(R^5)_2$ ,  $C(=O)SR^5$ , CN,  $NO_2$ , and  $SO_2R^5$ , such that Applicant must select a single substituent for A, and each subsequent variable position. In the instant case, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the

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claim that fall into the same class and subclass as the elected compound (or set of compounds).

5. Upon thorough consideration of the claims, the examiner has determined that a lack of unity of invention exists, as defined in Rule 13.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, **Part 1(a)**, indicates that the application should relate to only one invention, or if there is more than one invention, inclusion is permitted if they are so linked to form a single general inventive concept.

Annex B, **Part 1(b)**, indicates that "special technical features" means those technical features that as a whole define a contribution over the prior art.

Annex B, **Part 1(c)**, further defines independent and dependent claims. Unity of invention only is concerned in relation to independent claims. Dependent claims are defined as a claim that contains all the features of another claim and is in the same category as the other claim. The category of a claim refers to the classification of claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, **Part 1(e)**, indicates the permissible combinations of different categories of claims. **Part 1(e(i))** states that inclusion of an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said

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product, and an independent claim for a use of the said product is permissible.

Annex B, **Part 1(f)** indicates the "Markush practice" of alternatives in a single claim. **Part 1(f(i))** indicates the technical interrelationship and the same or corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, **Part 1(f(i-iii))**, the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure that is responsible for the common activity (or property). **Part 1(f(iv))** indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. **Part 1(f(v))** indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

6. The claims herein lack unity of invention under PCT Rule 13.1 and 13.2, since the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art. The compounds claimed contain a nitromethyl-alkyl-dicarbonyl backbone in common, which does not

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define a contribution over the prior art (**variables excluded**), please refer to the referenced WO 00/15599 document, which provides that the technical feature, which can be taken as a whole amongst all the alternatives, as depicted above, is not a 'special technical feature' as defined in PCT Rule 13.2, by failing to define a contribution over the prior art, as it was known in the art prior to the filing of the instant application. Please refer to Ji et al, WO 00/15599.

Further, under “Combinations of Different Categories of Claims {Annex B, Part 1(e)(I)}, Applicants are permitted a process for examination on the merits whereas Applicants are claiming several different processes. For example, improving insulin resistance is not the same method as treating impaired glucose tolerance, or treating hyperlipidemia, since all three disorders involve different intracellular mechanisms and different treatment protocol. Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

8. Applicant is reminded that upon the cancellation of claims to a non-elected

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invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANET L. COPPINS whose telephone number is (571)272-0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Coppins/  
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